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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,701	10/23/2000	Jang B. Rampal	1956-045	9837
22471	7590	06/02/2004	EXAMINER	
<b>PATENT LEGAL DEPARTMENT/A-42-C</b> BECKMAN COULTER, INC. 4300 N. HARBOR BOULEVARD BOX 3100 FULLERTON, CA 92834-3100				TUNG, JOYCE
ART UNIT		PAPER NUMBER		
		1637		
DATE MAILED: 06/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/694,701	RAMPAL ET AL.	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) claims 1-62, 64-66 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 29-42 and 55-62 is/are allowed.
- 6) Claim(s) 64-66 and 68-70 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ .   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

The applicant's response filed 2/3/2004 to the Office action has been entered.

Claims 1-62, 64-66 and 68-70 are pending. Claims 29-42, 55-62, 64-66 and 68-70 are examined.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/2004 has been entered.
  
2. The rejections of claims 29-42 and 55-62 under 35 U.S.C. 102(b) as being anticipated by Varma (5,622,826) and under 35 U.S.C. 103(a) further in view of Cremer et al. (6,197,501), Rampal et al. (6,013,789) are withdrawn.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- a. Claims 64-66 and 68-70 recite the limitation "target biopolymers" in claim 64. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 64-66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Fareed et al. (US 4,970,144, issued November 30, 1990).

Fareed et al. disclose a method of detecting a polypeptide contained in a sample comprising the steps of providing a modified substrate (See column 10, lines 19-29). A probe polypeptide can form a complex with the target polypeptide, contacting either the probe or target polypeptide to a surface of the substrate to form a probe assay article or a target assay article, contacting the probe assay article or target assay article with the probe peptide or target peptides to form a complex comprising the probe and the target polypeptides and then detecting and determining the presence of the complex (See column 11, lines 34-57). A protein solution is air-dried on the bottoms of wells (See column 11, lines 43-43 and column 13, lines 65-68). The test antigen can be 10-100 nanogram (See column 11, lines 38-43). This teaching is inherent to the limitations of claim 68.

Since Fareed et al. taught air-drying of a protein solution on the bottom of wells in microtiter dishes and unbound antibodies are removed by washing (See column 11, lines 34-48), the teachings of Fareed et al. anticipate the limitations of claims 64-66 and 68.

The response argues that Fareed et al. does not anticipate claim 29 (It should be claim 64) because they do not teach a modified surface and immobilization by adsorption

without additional fixing steps. However, Fareed et al. disclose that immobilized antibodies may be covalently or physically bound to the solid phase immunoabsorbent by techniques such as covalent bonding via an amide or ester linkage or by absorption (See column 10, lines 19-29). The teachings are inherent that the surface of the solid phase is modified and the immobilization is by absorption.

Moreover, the claim language of claim 64 states “modifying the surface of the substrate by introducing a functionality selected from a group consisting of amino group, carboxyl group, thiol group and their derivatives on the surface to obtain a modified surface”. Since the phrase “their derivatives” is interpreted as any functional group which modifies the surface of solid phrase, the teachings of Fareed et al. read on the limitations of the claims. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fareed et al. (US 4,970,144 issued November 13, 1990).

The teachings of Fareed et al. are set forth in section 4 above. Fareed et al. do not disclose specifically the aliquot amount of the probe or target needed and the time needed for air-drying the target polypeptide.

However, it would have been prima facie obvious for an ordinary skill in the art at the time of the instant invention to modify the reaction condition of Fareed et al. by optimizing the amount of the probes or target biopolymers used and the time for air drying the target biopolymer on the surface of substrate because optimization of a reaction condition was routine practice in the art at the time of the instant invention.

Moreover, since the amount of polynucleotide or polypeptide used as claimed is in a common range and the time needed for drying the sample is also in a common range, it would have been prima facie obvious for an ordinary skill in the art to choose these concentration and time for air-drying target polypeptide.

#### Summary

8. Claims 29-42 and 55-62 are allowable over the prior art and claims 64-66 and 68-70 are not allowable.

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9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112.

The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung TT  
May 26, 2004

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

5/27/04